APPROVAL OF FACILITIES TO EXPORT EQUINE SERUM AND EQUINE SERUM PRODUCTS TO THE EUROPEAN UNION

I. PURPOSE

The purpose of this document is to:

- Explain the European Union's (EU's) requirements for U.S. exports to the EU of equine serum and serum products;
- Standardize Animal and Plant Health Inspection Service (APHIS) field inspections of collection and processing facilities for these materials; and
- This document does not cover the serum of animals other than equines
- This document does not cover facilities approved by Veterinary Biologics. Exporting requesting information on exporting materials from facilities approved by Veterinary Biologics to the EU should be referred to Veterinary Biologics.

II. Background

REGULATION (EC) No. 1774/2002, published October 3, 2002, establishes the requirements for importing animal by-products not intended for human consumption into the EU.

The regulation requires APHIS to approve facilities exporting equine serum and products to the EU. To grant this approval, APHIS must consider items such as the serum source, and conditions of hygiene and storage at the processing facility.

Serum may be collected from horses slaughtered at Food Safety and Inspection Service (FSIS) inspected facilities, or collected from live horses at APHIS approved facilities.

If the blood is processed at a different location than the collection facility, APHIS must also approve the processing facilities.

Prior to APHIS inspecting facilities, the facilities are required to submit to APHIS for review documentation attesting that the facility meets minimum requirements. Following the pre-inspection review by the area office of this documentation, Veterinary Services (VS) will schedule inspections of the facility.

If an exporter wishes to export a blood product on a certificate which makes reference to Regulation (EC) No. 1774/2002, then the product must be exported from a facility inspected and approved under this package. **Most finished packaged "ready for the end user" items are exempt from this regulation and do not require 1774 certification. The exporter must have their importer in the EU contact the pertinent authorities in the importing member country to determine if 1774 certification is required for their product.**

Once approval is granted, the facility must be inspected at least once every 365 days to maintain their approval.

III. Definition

Approved facility: In this document, this term will apply to facilities approved by APHIS to collect equine blood/serum, to process equine blood, serum, or products, or to export these materials to the EU.

IV. REQUIREMENT THAT ALL SERUM BE SOURCED FROM APPROVED FACILITIES

For suppliers other than slaughterhouses, area offices should ensure that all suppliers have been granted approval by NCIE and are included in the list of approved facilities (available in the "Information Dissemination Electronic Access (IDEA) System)." From the IDEA home page, located at http://inside.aphis.usda.gov/property/apps/idea.html, the area office should select "Approved Animal Product Export Facilities" (http://inside.aphis.usda.gov/authority/ncie/query-rpfdbs.html). The Area office should then select "Approved Export Facilities under EU Regulation 1774/2002" in the search criteria.

V. EXPORT CERTIFICATION OF EQUINE SERUM AND SERUM PRODUCTS TO THE EU

Prior to endorsing export certificates to the EU, area offices should ensure that the processing facilities have been granted final approval by NCIE and are included in the list of facilities (available in the "Information Dissemination Electronic Access (IDEA) System."

VI. VETERINARY SUPERVISION

- **Blood collected from slaughtered animals**

Serum sourced from slaughter facilities must be collected from animals which passed ante-mortem examination.

- **Blood collected from live animals**

Serum must be collected from animals under veterinary supervision. These animals must not have shown signs of infectious disease at the time of collection. VS must confirm by inspection that approved facilities have a veterinarian examine each animal at least once every 30 days to ensure that blood is only collected from animals not showing signs of infection diseases.

The facility must minimally have records showing that an accredited veterinarian examines each animal at least once every thirty days. The facility must also have in place a written Standard Operating Procedure (SOP) detailing the daily supervision of the animals by facility personal. This SOP must state under what circumstances an animal is removed from the pool of source animals pending veterinary examination, or under what circumstances a more frequent (more than once every 30 days) veterinary examination is conducted. This SOP must ensure that an animal whose clinical appearance changes significantly after the last veterinary examination is not bled again until following another veterinary examination.

VII. DISEASE STATUS

The animals must either never have been present at facilities ever quarantined for any disease, or have been present at the collection facility (or a farm also free of these diseases for the indicated time period) for the indicated time periods prior to collection:

- Equine encephalomyelitis (6 months after last clinical animal was removed),
- Infectious anemia (all infected animals have been removed, and all remaining ones had two negative Coggins tests- 3 months apart),
- Vesicular stomatitis (6 months),
- Rabies (one month after last recorded case),
- Anthrax (15 days after the last recorded case).

If the inspector has any doubt about the status of disease prohibitions on the facility, the Area Veterinarian in Charge should be able to obtain the information from the State veterinarian.

If a facility has been under quarantine for any of the above diseases, all susceptible animals must have been removed, and the facility disinfected at least 30 days prior to collection (or, in the case of anthrax, 15 days).

REQUIREMENTS FOR WHEN A FACILITY HAS BEEN QUARANTINED FOR ONE OF THESE DISEASES	
Disease	Requirement
Equine encephalomyelitis	6 months after the slaughter of all cases
Vesicular stomatitis	6 months after the lifting of the quarantine
Rabies	1 month after the last recorded case
Anthrax	15 days after the last recorded case
Infectious anemia	After all cases have been removed, source animals must have shown a negative reaction to two Coggins tests carried out three months apart

VIII. HYGIENE AND STORAGE

The regulation requires APHIS to approve both conditions of hygiene and storage at processing facilities.

IX. PRE-INSPECTION PROCEDURES

Prior to scheduling the inspection of the facility, the area office should forward this document to the plant management.

Prior to VS inspection of the plant, plant management must forward to the area office, a **Notarized Approved Supplier Form**.

The area office should confirm that this form has been provided and meets all requirements. The form must be notarized and must list the position that the signatory holds in the company. The position title should indicate that the individual could be expected to have knowledge of the information included in the notarized form. For example, the form should not be endorsed by the labeling officer. This form should be updated (signed and provided to the Area office) every year.

The form must:

- Identify the facilities where the blood is collected;
- Be the precise “Notarized Approved Supplier Form ” located in this document;
- Verify that blood is collected from animals under veterinary supervision.

X. INSPECTION PROCEDURES

Prior to arriving at the plant for the inspection, the inspector should review the Notarized Approved Supplier Form already sent to the area office and the inspection checklist.

The inspection should begin in the plant management office. The following documents should be reviewed with plant management at this time:

- Notarized Approved Supplier Form;
- Written SOP referenced in Section VI above;
- Records of veterinary examination of the horses; and
- For inspection renewal of export facilities, records showing the production of each lost of material certified for export to the EU over the past year.

The inspector may then wish to go over the checklist with a plant tour guide to establish that all questions should be addressed during the tour. The guide should then take the inspector through the facility, addressing each item on the checklist. At the end of the tour, the inspector should ask the guide to return to any areas necessary, or to show the evidence for any unanswered questions.

XI. BILLING FOR INSPECTIONS

Inspections to approve facilities to process blood and blood products to be used for technical purposes, including pharmaceuticals, in vitro diagnosis, and laboratory agents for export to the EU will be billed by the hour (Title 9, Code of Federal Regulations, Parts 156 and 130).

XII. FILING OF INSPECTION REPORTS

A copy of the *completed* inspection form and the Notarized Approved Supplier Form should be sent to NCIE, Attention: Products Export Team, facsimile number 301-734-8226. The checklist will indicate which documents are to be forwarded to NCIE. All blanks should be completed legibly. If notes taken during the inspection are not legible, the inspection form should either be typed or completed again, in clear block letters. A copy of the inspection package should be maintained at the area office.

The facility is not approved to export to the EU until NCIE has processed the checklist package and provided final approval. Prior to endorsing any export certificates, the area office should refer to the list of approved facilities available on the "Information Dissemination Electronic Access (IDEA) System." From the IDEA home page, located at http://inside.aphis.usda.gov/property/apps/idea.html, the area office should select "Approved Animal Product Export Facilities" (http://inside.aphis.usda.gov/authority/ncie/query-rpfdbs.html). The Area office should then select "Approved Export Facilities under EU Regulation 1774/2002" in the search criteria.

NOTE: The information contained in the above referenced area of the APHIS Intranet is proprietary. Area offices may confirm to third parties whether or not facilities are approved .

XIII. APPROVAL NUMBERS

Facility approval numbers are issued by NCIE. VS should not endorse any export certificate for blood products being exported to the EU, UNLESS the facility approval number listed on the certificate is the same as the number listed in the IDEA system.

XIV. FACILITY NAME OR ADDRESS CHANGES

Facilities must notify NCIE directly of changes to names or mailing addresses. This notification should be sent NCIE, Attention: Products Export Team, facsimile number 301-734-8226. Facilities should also copy the AVIC on this request.

"Mailing address" refers to a change in the street address for the same physical building. If a facility's physical address changes, the new facility will need to be inspected.

APPENDIX ONE

NOTARIZED APPROVED SUPPLIER FORM

This serves to inform officials of the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) that _____ (Plant's name), located at _____

_____

(Plant's street address, including City, State, and Zip): (check all that apply)

___ I. Is a blood collection facility where horse blood for export to the EU is only collected from animals not showing signs of clinical disease which are under the supervision of an accredited veterinarian. These animals are examined by an accredited Veterinarian at least once every 30 days. The facility has in place a Standard Operating Procedure (SOP) to ensure that animals are re-examined by an accredited veterinarian prior to bleeding, if they show any significant clinical variation from their last veterinary examination.

___ II. Is an equine blood or serum processing/export facility which only receives blood or blood products to be processed for eventual export to the EU that was collected from horses at facility approved by APHIS, the Food Safety and Inspection Service (FSIS), or a State Approved Slaughter facility. These facilities are:

Facility Name	City, State	APHIS, FSIS, or State Slaughter Facility Approval #

I certify that the statements listed above are true to the best of my knowledge and belief.

Signed by: _____ Date: _____

Printed name of signing official: _____

Position of signing official: _____--

Company name: _____

Company phone number: _____

Notary signature: _____

APPENDIX TWO

U.S. Plant Inspection Checklist for APPROVAL OF FACILITIES TO COLLECT AND/OR PROCESS EQUINE BLOOD AND BLOOD PRODUCTS FOR EXPORT TO THE EUROPEAN UNION

1. Animal and Plant Health Inspection Service (APHIS) Approval Number (This blank should be left blank for newly inspected facilities): _____

2. Plant/company name: _____.

3. Address of location being inspected:
_____
_____
_____

4. Address of headquarters if different from:
_____
_____
_____

5. Contact person at plant: Name _____, Telephone _____, Facsimile _____.

6. Is the facility a (check all that apply):

____ blood collection facility

____ intermediate supplier facility (does not collect or export blood)

____ blood export facility

7. ___ Yes ___ No ___ N/A If the facility is a blood collection facility, has the facility been under any quarantine for equine encephalomyelitis within the last six months?

8. ___ Yes ___ No ___ N/A If the facility is a blood collection facility, has the facility been under any quarantine for infectious anemia? If yes, please provide details.

9. ___ Yes ___ No ___ N/A If the facility is a blood collection facility, has the facility been under any quarantine for vesicular stomatitis in the last six months?

10. ___ Yes ___ No ___ N/A If the facility is a blood collection facility, has the facility been under any quarantine for rabies in the last month?

11. ___ Yes ___ No ___ N/A If the facility is a blood collection facility, has the facility been under any quarantine for anthrax within the last 15 days?

12. ___ Yes ___ No ___ N/A If the facility has been under quarantine for equine encephalomyelitis, infectious anemia, vesicular stomatitis, rabies, or anthrax, was the facility disinfected after the removal of all susceptible animals, at least 30 days (15 in the case of anthrax) prior to the collection of the blood?

13. ___ Yes ___ No ___ N/A If the facility receives blood or blood products collected from horses at a slaughter facility, have you confirmed that the slaughter facility is located in an area that meets the requirements listed in questions 7,8,9,10, and 11 above?

14. ___ Yes ___ No If the facility collects blood from horses that have not been on site for at least 6 months, have you verified that the facility has records for these animals showing that they have only been kept in areas meeting the criteria of questions 7,8,9,10, and 11 above?

15. ____ Yes ____ No Is this a facility which exports product directly to the EU? If yes, please list the products exported to the EU:

_____

_____

_____

16. If the facility supplies blood or blood component to another facility in the US for further processing or for export, please list the products supplied here:

_____

_____

_____

17. ___ Yes ___ No Has the plant provided you with a **current NOTARIZED APPROVED SUPPLIER FORM**? Please attach to this checklist and forward to NCIE.

18. ___ Yes ___ No ___ N/A If the facility is a blood collection facility, did you review the plant's written SOP which appeared adequate to ensure that animals showing signs of clinical disease are re-examined by a veterinarian prior to bleeding?

19. ___ Yes ___ No Did you observe any obviously unhygienic conditions during your inspection? (Attach explanation if answering "yes.")

20. ___ Yes ___ No Does the plant appear to have adequate storage space and equipment to meet its needs?

21. ____ Yes ___ No ___ N/A If the facility is a blood collection facility, did you review veterinary records showing each animal has been examined by a veterinarian at least once every 30 days?

22. ___ Yes ___ No Does the plant package product for export to the EU in sealed impermeable containers clearly labeled "SERUM FROM EQUIDAE" which bear the registration number of the blood collection facility

23. Comments:

_____
_____
_____
_____

24. Recommendation for approval to (check all that apply)

___ Collect horse blood for eventual export to the EU

___ Be an intermediate supplier of horse blood for eventual export to the EU

___ Export horse blood/serum to the EU

_____ _____
Approve Disapprove

_____
Printed name of inspector

_____ _____
Signature of Inspector Inspection Date

_____ _____
Signature of Veterinarian in Charge concurring With recommendation in number 24. Date

Please forward a copy of the completed form and all required notarized forms to the National Center for Import and Export, Animal and Plant Health Inspection Service, 4700 River Rd., Unit 40, Riverdale, MD 20737-1231 (telephone: 301-734-3277; fax: 301-734-8226).

Note: To maintain approval, facilities must be inspected at least once every 12 months.